

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SCIELE PHARMA, INC.,	)	
ANDRX CORPORATION, ANDRX	)	
PHARMACEUTICALS, INC. (N/K/A	)	
WATSON LABORATORIES, INC.-	)	
FLORIDA), ANDRX PHARMACEUTICALS,	)	C.A. No. 09-037 (RBK)(JS)
L.L.C., ANDRX LABORATORIES (NJ),	)	CONSOLIDATED
INC., ANDRX EU LTD., AND ANDRX	)	
LABS, L.L.C.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
LUPIN LTD., and	)	
LUPIN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

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SHIONOGI PHARMA, INC.,	)	
ANDRX CORPORATION, ANDRX	)	
PHARMACEUTICALS, INC. (N/K/A	)	
WATSON LABORATORIES, INC.-	)	
FLORIDA), ANDRX PHARMACEUTICALS,	)	
L.L.C., ANDRX LABORATORIES (NJ),	)	
INC., ANDRX EU LTD., AND ANDRX	)	
LABS, L.L.C.,	)	
	)	C.A. No. 10-135 (RBK)(JS)
Plaintiffs,	)	
	)	
v.	)	
	)	
MYLAN, INC., and	)	
MYLAN PHARMACEUTICALS INC.,	)	
	)	
Defendants.	)	

**PLAINTIFFS' ANSWER TO THE LUPIN DEFENDANTS' COUNTERCLAIMS**

Plaintiffs Sciele Pharma, Inc./Shionogi Pharma, Inc. (“Shionogi”), and Andrx Corporation, Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc.-Florida), Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc., Andrx EU Ltd., and Andrx Labs, L.L.C.

(collectively “Andrx” and collectively with Shionogi “Plaintiffs”) answer the counterclaims of Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively “Lupin”), using the paragraph numbers set forth within Lupin’s Amended Answer and Counterclaims dated February 13, 2012.

**THE PARTIES**

67. Upon information and belief, admitted.

68. Upon information and belief, admitted.

69. Admitted that Sciele Pharma, Inc. (n/k/a Shionogi Pharma Inc.) is a Delaware corporation, having a place of business at Five Concourse Parkway, Suite 1800, Atlanta, Georgia 30328. Otherwise denied.

70. Plaintiffs admit that Andrx Corporation is a Delaware corporation and subsidiary of Watson Pharmaceuticals, Inc., having a place of business at 4955 Orange Drive, Davie, Florida 33314 and that Andrx Pharmaceuticals, L.L.C. and Andrx Labs, L.L.C. are Delaware limited liability companies and subsidiaries of Andrx Corp., having a place of business at 4955 Orange Drive, Davie, Florida 33314 and that Andrx Laboratories (NJ), Inc. is a Delaware corporation and a subsidiary of Andrx Corp., having a place of business at 8151 Peters Road, 4th Floor, Plantation, Florida 33324 and that Andrx EU Limited is a UK corporation and subsidiary of Andrx Corp., having a place of business at 8151 Peters Road, 4th Floor, Plantation, Florida 33324. The remaining allegations in Paragraph 70 are denied.

71. Plaintiffs admit that Andrx is the owner of the ’859 patent.
72. Plaintiffs admit that Andrx is the owner of the ’886 patent.
73. Plaintiffs admit that Andrx is the owner of the ’162 patent.
74. Plaintiffs admit that Andrx is the owner of the ’459 patent.

**JURISDICTION AND VENUE**

75. Paragraph 75 contains legal conclusions and allegations as to which no response is required. To the extent an answer is deemed required, Plaintiffs admit that Lupin purports to base its Counterclaims on the specified sections of the United States Code. The allegations are otherwise denied.

76. Paragraph 76 contains legal conclusions and allegations as to which no response is required. To the extent an answer is deemed required, Plaintiffs admit that there is now an actual and justiciable controversy between them and Lupin concerning the '859 and '866 patents and that this Court has subject matter jurisdiction over Counts I, II, V, and VII of Lupin's Counterclaims. The remaining allegations in Paragraph 76 are denied.

77. Paragraph 77 contains legal conclusions and allegations as to which no response is required. To conserve the resources of the Court and the parties, and solely for the limited purpose of this action, Plaintiffs do not contest that venue is proper in this district.

**THE ALLEGED CONTROVERSY**

78. Upon information and belief, admitted.

79. Admitted.

80. Admitted that Andrx Labs, LLC is listed as the holder of NDA No. 21-574 for Fortamet® brand metformin hydrochloride extended release tablets and that the '459, '162, '866, and '859 patents are listed in the Orange Book for Fortamet® brand metformin hydrochloride extended release tablets. The remaining allegations in Paragraph 80 are denied.

81. Paragraph 81 contains legal conclusions and allegations as to which no response is required. To the extent a response is deemed required, admitted that the Complaint Plaintiffs filed in this District does not allege that Lupin infringed or will infringe the '162 or '459

patents, and that there is an actual and justiciable controversy between Plaintiffs and Lupin concerning the '859 and '866 patents. The remaining allegations in Paragraph 81 are denied.

**COUNTERCLAIM COUNT I**

82. Plaintiffs repeat and reassert all responses to Paragraphs 67-81 as if they were stated fully herein.

83. Denied.

84. Denied.

**COUNTERCLAIM COUNT II**

85. Plaintiffs repeat and reassert all responses to Paragraphs 67-84 as if they were stated fully herein.

86. Denied.

87. Denied.

**COUNTERCLAIM COUNT III**

88. Plaintiffs repeat and reassert all responses to Paragraphs 67-87 as if they were stated fully herein.

89. Plaintiffs deny that there is an actual and justiciable controversy with respect to the '162 Patent, and thus, deny the allegations in Paragraph 89.

**COUNTERCLAIM COUNT IV**

90. Plaintiffs repeat and reassert all responses to Paragraphs 67-89 as if they were stated fully herein.

91. Plaintiffs deny that there is an actual and justiciable controversy with respect to the '459 Patent, and thus, deny the allegations in Paragraph 91.

**COUNTERCLAIM COUNT V**

92. Plaintiffs repeat and reassert all responses to Paragraphs 67-91 as if they were stated fully herein.

93. Denied.

**COUNTERCLAIM COUNT VI**

94. Plaintiffs repeat and reassert all responses to Paragraphs 67-93 as if they were stated fully herein.

95. Plaintiffs deny that there is an actual and justiciable controversy with respect to the '459 Patent, and thus, deny the allegations in Paragraph 95.

**COUNTERCLAIM COUNT VII**

96. Plaintiffs repeat and reassert all responses to Paragraphs 67-95 as if they were stated fully herein.

97. Denied.

**COUNTERCLAIM COUNT VIII**

98. Plaintiffs repeat and reassert all responses to Paragraphs 67-97 as if they were stated fully herein.

99. Plaintiffs deny that there is an actual and justiciable controversy with respect to the '162 Patent, and thus, deny the allegations in Paragraph 73.

**RESPONSE TO LUPIN'S PRAYER FOR RELIEF**

No response is required to Lupin's Prayer for Relief. To the extent that a response is deemed required, Plaintiffs deny that Lupin is entitled to any relief whatsoever.

**AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

Lupin's Counterclaims fail to state a claim upon which relief can be granted.

## SECOND AFFIRMATIVE DEFENSE

Plaintiffs reserve all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the patent laws of the United States and any other defenses, at law or in equity, that may now exist or in the future be available based on discovery and further factual investigation of this case.

## PRAYER FOR RELIEF

WHEREFORE, upon final hearing or trial, Plaintiffs pray for the following relief:

- (a) That the Court dismiss Lupin's Counterclaims with prejudice;
- (b) That the Court enter judgment on Lupin's Counterclaims in favor of Plaintiffs;
- (c) That the Court award Plaintiffs the relief sought in their Amended and Supplemental Complaint;
- (d) That the Court award Plaintiffs their costs and attorneys' fees in defending against the Counterclaims; and
- (e) That the Court award Plaintiffs such other costs and further relief as the Court deems just, equitable, and appropriate.

RICHARDS, LAYTON & FINGER P.A.

*/s/ Steven J. Fineman*

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March 8, 2012  
5801236

**CERTIFICATE OF SERVICE**

I hereby certify that on March 8, 2012, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following all registered participants.

I also certify that copies were caused to be served on March 8, 2012 upon the following in the manner indicated:

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